

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

TALECRIS BIOTHERAPEUTICS, INC., and  
BAYER HEALTHCARE LLC,

Plaintiffs,

v.

BAXTER INTERNATIONAL INC., and  
BAXTER HEALTHCARE CORPORATION,

Defendants.

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BAXTER HEALTHCARE CORPORATION

Counterclaimant,

v.

TALECRIS BIOTHERAPEUTICS, INC., and  
BAYER HEALTHCARE LLC,

Counterclaim Defendants.

C.A. No. 05-349-GMS

PRELIMINARY JURY INSTRUCTIONS

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## **1 INTRODUCTION**

Members of the jury: Now that you have been sworn, I am now going to give you some preliminary instructions to guide you in your participation in the trial.

These instructions will give you some general rules and guidance that might apply to any civil case. However, because this is a patent trial which will deal with subject matter that is not within the every day experience of most of us, we will also watch a video that gives an overview of the patent system and I will also give you some preliminary instructions, which will assist you in discharging your duties as jurors.

## **2 THE PARTIES AND THEIR CONTENTIONS**

Before I begin with those instructions, however, allow me to give you an overview of who the parties are and what each contends.

You may recall that during the process that led to your selection as jurors, I advised you that this is a civil action for patent infringement arising under the patent laws of the United States.

The parties in this case are the plaintiffs Talecris Biotherapeutics, Inc. and Bayer Healthcare LLC. The defendants in this case are Baxter International Inc. and Baxter Healthcare Corporation. I will refer to both of the plaintiffs collectively as “Talecris,” and I will refer to both of the defendants collectively as “Baxter” unless I or the attorneys tell you otherwise. The dispute between the parties relates to Baxter’s process of manufacturing immunoglobulin product that is administered intravenously, also known as an “IGIV” or “IVIG” product, called GAMMAGARD® Liquid. You may know or have heard of these IGIV products for people with immune deficiency conditions whose bodies cannot adequately fight off infections. IGIV products provide a type of antibody to help them fight off infections. During the trial, the parties will offer testimony to familiarize you with the technology for manufacturing this product and the product itself.

Bayer Healthcare owns United States Patent No. 6,686,191, and Talecris Biotherapeutics is the licensee of the patent. Talecris alleges that United States Patent No. 6,686,191 is infringed by Baxter. Because patent numbers are so long, patents are usually referred to by their last three digits. In this case, you will hear the parties refer to Patent No. 6,686,191 as simply “the ‘191 patent”. Talecris contends that Baxter imports its GAMMAGARD® Liquid product into the

United States and/or offers to sell, sells, or uses GAMMAGARD® Liquid in the United States and that the GAMMAGARD® Liquid product is manufactured using a process that infringes the '191 patent. Talecris also contends that such infringement is willful. I, and the attorneys and witnesses, may refer to Baxter's process for making GAMMAGARD® Liquid as the "accused process." Talecris seeks damages for Baxter's alleged infringement.

Talecris does not contend that all of the claims of the '191 patent are infringed by Baxter. Instead, Talecris asserts that only certain claims are infringed. They may be called "asserted claims." You, of course, will determine whether or not Baxter's accused process infringes the asserted claims of the '191 patent.

Persons or companies sued for allegedly infringing a patent can deny infringement. They can also defend a charge of infringement by proving the claims of the patent are invalid or unenforceable. In this case, Baxter denies that it infringes the '191 patent and asserts what are called affirmative defenses to the charge of infringement. I will give you further instructions as to charges of infringement, invalidity, unenforceability, and possible damages resulting from a finding of infringement at the close of the evidence.

**3 DUTIES OF THE JURY**

So, let me begin with those general rules that will govern the discharge of your duties as jurors in this case.

It will be your duty to find from the evidence what the facts are. You and you alone will be the judges of the facts. You will then have to apply those facts to the law as I will give it to you both during these preliminary instructions and at the close of the evidence. You must follow that law whether you agree with it or not. In addition to instructing you about the law, at the close of the evidence, I will provide you with instructions as to what the claims of the patent mean. Again, of course, you are bound by your oath as jurors to follow these and all the instructions that I give you, even if you personally disagree with them. All the instructions are important, and you should consider them together as a whole.

Perform these duties fairly. Do not let any bias, sympathy, or prejudice that you may feel toward one side or the other influence your decision in any way. Also, do not let anything that I may say or do during the course of the trial influence you. Nothing that I may say or do is intended to indicate, or should be taken by you as indicating, what your verdict should be.

#### **4 EVIDENCE**

The evidence from which you will find the facts will consist of the testimony of witnesses, which means the answers of the witnesses to questions posed by the attorneys or the Court. Evidence will also consist of documents and other things received into the record as exhibits, and any facts that the lawyers agree to or stipulate to or that I may instruct you to find.

Certain things are not evidence and must not be considered by you. I will list them for you now:

1. Statements, arguments, and questions by lawyers are not evidence.
2. Objections to questions are not evidence. Lawyers have an obligation to their clients to make objections when they believe evidence being offered is improper under the Rules of Evidence. You should not be influenced by the objection or by the Court's ruling on it. If the objection is sustained, ignore the question. If it is overruled, treat the answer like any other. If you are instructed that some item of evidence is received for a limited purpose only, you must follow that instruction.
3. Testimony that the Court has excluded or told you to disregard is not evidence and must not be considered.
4. Anything you may have seen or heard outside the courtroom is not evidence and must be disregarded. You are to decide the case solely on the evidence presented here in the courtroom.

## **5 DIRECT AND CIRCUMSTANTIAL EVIDENCE**

There are two kinds of evidence: direct and circumstantial. Direct evidence is direct proof of a fact, such as the testimony of an eye witness. If a witness testified that he saw it was raining outside, and you believed him, that would be direct evidence that it was raining.

Circumstantial evidence is proof of facts from which you may infer or conclude that other facts exist. If someone walked into the courtroom wearing a raincoat covered with drops of water and carrying a wet umbrella, that would be circumstantial evidence from which you could conclude that it was raining.

As a general rule, the law makes no distinction between these two types of evidence, but simply requires that you find facts from all the evidence in the case, whether direct or circumstantial or a combination of the two.



## **6 DEPOSITIONS AS SUBSTANTIVE EVIDENCE**

In some instances during this trial, you may hear testimony in the form of reading a deposition transcript or the playing of videotape excerpts from the deposition. A deposition is the sworn testimony of a witness taken before trial. The witness is placed under oath and swears to tell the truth, and the lawyers for each party may ask questions. A court reporter is present and records the questions and answers.

Deposition testimony is entitled to the same consideration and is to be judged, insofar as possible, in the same way as if the witness had been present to testify.

**7 USE OF WRITTEN DISCOVERY OF A PARTY**

In some instances during this trial, you may hear answers that one of the parties gave in response to written questions submitted by the other side. The written questions are called “interrogatories” or “requests for admission”. The written answers were given in writing and under oath, before the trial.

You must consider these answers to interrogatories and requests for admission in the same manner as if the answers were made from the witness stand.

**8 CREDIBILITY OF WITNESSES - WEIGHING CONFLICTING TESTIMONY**

You are the sole judges of each witness' credibility. You should consider each witness' means of knowledge; strength of memory; opportunity to observe; how reasonable or unreasonable the testimony is; whether it is consistent or inconsistent; whether it has been contradicted; the witness' biases, prejudices, or interests; the witness' manner or demeanor on the witness stand; and all circumstances that, according to the evidence, could affect the credibility of the testimony.

If you find the testimony to be contradictory, you must try to reconcile it, if reasonably possible, so as to make one harmonious story of it all. But if you can't do this, then it is your duty and privilege to believe the testimony that, in your judgment, is most believable and disregard any testimony that, in your judgment, is not believable. This instruction applies to the testimony of all witnesses, including expert witnesses.

## **9 EXPERT WITNESSES**

An expert witness is a person who has special knowledge, skill, education, training, or experience in a technical field who is permitted to state an opinion on scientific, technical, or specialized matters when such scientific, technical, or specialized knowledge may be helpful to the jury. The value of this kind of testimony depends upon the qualifications and skill of the witness, the sources of the witness' information, and the reasons supplied for any opinions given. You should consider this kind of testimony like all other testimony you hear and weigh it by the same tests.

## 10 BURDEN OF PROOF

As I have already told you, in this case, Bayer Healthcare is the owner and Talecris Biotherapeutics is the licensee of the '191 patent, which they contend Baxter infringes. Talecris, therefore, has the burden of proving infringement by what is called a preponderance of the evidence. That means Talecris has to produce evidence which, considered in the light of all the facts, leads you to believe that what Talecris alleges is more likely true than not. To put it differently, if you were to put Talecris' and Baxter's evidence on opposite sides of a scale, the evidence supporting Talecris' allegations would have to make the scale tip somewhat on its side. If Talecris fails to meet this burden, the verdict must be for Baxter. Talecris must also prove its damages by a preponderance of the evidence.

Talecris also contends that Baxter willfully infringed the '191 patent. Talecris must prove willful infringement by clear and convincing evidence. Clear and convincing evidence is evidence that produces an abiding conviction that the truth of a factual contention is highly probable. Proof by clear and convincing evidence is thus a higher burden than proof by a preponderance of the evidence.

In this case, Baxter asserts that Talecris' patent is invalid and unenforceable. A patent, however, is presumed to be valid. Accordingly, Baxter has the burden of proving by clear and convincing evidence that the '191 patent is invalid and unenforceable.

Finally, keep in mind that the standard in criminal cases, "proof beyond a reasonable doubt" does not play any part in this case; therefore, you should put it out of your mind.

## 11 SUMMARY OF THE PATENT ISSUES

In this case, you must decide several things according to the instructions that I will give you at the end of the trial. Those instructions will repeat this summary and will provide more detail. One thing you will not decide is the meaning of the patent claims. That is one of my jobs - to explain to you what the patent claims mean. By the way, the word "claims" is a term of art and I will instruct you on its meaning at trial's end. Meanwhile, you will find a definition in the glossary attached to these preliminary instructions. In essence, you must decide:

1. Whether Talecris has proven by a preponderance of the evidence that Baxter infringes claim 7 of the '191 patent by importing into the United States, and/or offering to sell, selling, or using within the United States Baxter's GAMMAGARD® Liquid product which Talecris alleges is made by the '191 patented process;
2. If you find that claim 7 of the '191 patent is infringed, whether Talecris has proven by clear and convincing evidence that Baxter's infringement of the '191 patent was willful;
3. Whether Baxter has proven by clear and convincing evidence that claims 1 and 7 of the '191 patent are invalid;
4. Whether Baxter has proven by clear and convincing evidence that the '191 patent is unenforceable;
5. If you find that claim 7 is infringed and valid and the '191 patent is enforceable, whether Talecris has proven its measure of damages by a preponderance of the evidence.

**12 CONDUCT OF THE JURY**

Now, a few words about your conduct as jurors.

First, I instruct you that during the trial you are not to discuss the case with anyone or permit anyone to discuss it with you. Until you retire to the jury room at the end of the case to deliberate on your verdict, you simply are not to talk about this case. If any lawyer, party, or witness does not speak to you when you pass in the hall, ride the elevator, or the like, remember it is because they are not supposed to talk with you nor you with them. In this way, any unwarranted and unnecessary suspicion about your fairness can be avoided. If anyone should try to talk to you about it, bring it to the Court's attention promptly.

Second, do not read or listen to anything touching on this case in any way.

Third, do not try to do any research or make any investigation about the case on your own.

Finally, do not form an opinion until all the evidence is in. Keep an open mind until you start your deliberations at the end of the case.

During the trial, I will permit you to take notes. A word of caution is in order. There is always a tendency to attach undue importance to matters which one has written down. Some testimony, which is considered unimportant at the time presented, and thus not written down, takes on greater importance later in the trial in light of all the evidence presented. Therefore, you are instructed that your notes are only a tool to aid your own individual memory, and you should not compare your notes with other jurors in determining the content of any testimony or in evaluating the importance of any evidence. Your notes are not evidence, and are by no means a complete outline of the proceedings or a list of the highlights of the trial. Above all, your

memory should be your greatest asset when it comes time to deliberate and render a decision in this case.

So, if you do take notes, leave them in your seat at the end of the day, and my Deputy will collect them and return them to your seat the next day. And, remember that they are for your own personal use.

I will give you detailed instructions on the law at the end of the case, and those instructions will control your deliberations and decision.



### **13 COURSE OF THE TRIAL**

This trial, like most jury trials, comes in seven stages or phases. We have already been through the first phase, which was to select you as jurors. The remaining stages are:

2. These preliminary instructions to you;
3. Opening statement which are intended to explain to you what each side intends to prove and are offered to help you follow the evidence. The lawyers are not required to make opening statements at this time, or they may defer this opening until it is their turn to present evidence;
4. The presentation of the evidence which will include live witnesses and may also include previously recorded testimony, as well as documents and things;
5. My final instructions on the law to you;
6. The closing arguments of the lawyers which will be offered to help you make your determination; and, finally,
7. Your deliberations where you will evaluate and discuss the evidence among yourselves and determine the outcome of the case.

Please keep in mind that evidence is often introduced somewhat piecemeal. So, as the evidence comes in, you as jurors need to keep an open mind.

We will begin shortly, but first I want to outline the anticipated schedule of the trial.

**14 TRIAL SCHEDULE**

Though you have heard me say this during the voir dire, I want to again outline the schedule I expect to maintain during the course of this trial. This case is expected to take 7 days to try. We will normally begin the day at 9:00 A.M. promptly. We will go until 1:00 P.M. and, after a one hour break for lunch, from 2:00 P.M. to 4:30 P.M. There will be a fifteen minute break at 11:00 A.M. and another fifteen minute break at 3:15 P.M. The only significant exception to this schedule may occur when the case is submitted to you for your deliberations. On that day, the proceedings might last beyond 5:00 P.M. We will post a copy of this schedule for your convenience in the jury room.

## 15 GLOSSARY OF PATENT TERMS

<u>Applicant</u>	The named inventor who is applying for a patent.
<u>Assignment</u>	Transfer of ownership rights in a patent or patent application from one person or company to another.
<u>Claims</u>	The part of a patent that defines the invention. These are found at the end of the patent specification in the form of numbered paragraphs.
<u>Disclosure of Invention</u>	The part of the patent specification that explains how the invention works and usually includes one or more figures.
<u>File Wrapper, File History or Prosecution History</u>	The written record of proceedings in the United States Patent and Trademark Office ("Patent Office" or "PTO"), including the original patent application and later rejections, responses to the rejections, amendments, and other communications between the Patent Office and the applicant.
<u>Patent Application</u>	The initial papers filed in the Patent Office by an applicant. These typically include a specification, drawings, claims, and the oath (declaration) of the applicant.
<u>Patent Examiners</u>	Personnel employed by the Patent Office having expertise in various technical areas who review (examine) patent applications to determine whether the claims of a patent application are patentable and whether the disclosure adequately describes the invention.
<u>Prior Art</u>	Any information that is used to describe public, technical knowledge prior to the invention by the applicant or more than a year prior to the filing of his/her patent application.
<u>Prior Art References</u>	Any item of prior art (publication, patent or product) used to determine patentability.
<u>Specification</u>	The part of the patent application or patent that describes the invention, and may include drawings. The specification does not define the invention; only the claims do.

## 16 GLOSSARY OF ABBREVIATIONS AND PRODUCTS

Abbreviation	Term
'191 Patent	U.S. Patent No. 6,686,191
ACA	anticomplement activity
Alonso Patent	U.S. Patent No. 6,686,191
BLA	Biological License Application
BRP	Biological Reference Preparation
EP	European Pharmacopoeia
EMEA	European Medicines Agency
FDA	U.S. Food and Drug Administration
GG	GAMMAGARD®
IgA	immunoglobulin-A
IgG	immunoglobulin-G
IgM	immunoglobulin-M
IND or INDA	Investigational New Drug Application
IVIG	intravenous immunoglobulin
IGIV	
ISG	immune serum globulin
IV	Intravenous
IM	Intramuscular
MSD	Molecular Size Distribution
PLA	Product License Application
PTO	U.S. Patent and Trademark Office
S/D	solvent/detergent
TVR	Triple Virally Reduced

<b><u>Bayer's/Talecris'</u></b> <b><u>IGIV Products:</u></b> Gamimune® N Gamimune® N S/D Gamunex®	<b><u>Baxter's/Immuno's IGIV</u></b> <b><u>Products:</u></b> ENDOBULIN® ENDOBULIN® S/D IVEEGAM™ EN GAMMAGARD® GAMMAGARD® S/D GAMMAGARD® Liquid	<b><u>Other Companies' IGIV Products:</u></b> Carimune® Flebogamma® Octagam® Panglobulin® Partobulin Polygam® Polygam® S/D SANDOGLOBULIN® Venoglobulin-S
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**17 GENERAL GUIDANCE REGARDING PATENTS**

It is intended that the Federal Judicial Center video entitled “An Introduction To The Patent System” will be shown here. A text copy of the video is attached as Appendix A hereto.

**CERTIFICATE OF SERVICE**

I hereby certify on this 7th day of May, 2007 I electronically filed the foregoing **Preliminary Jury Instructions** with the Clerk of Court using CM/ECF which will send notification of such filing to the following:

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I also hereby certify that a true copy of the foregoing document was served upon the following in the manner indicated on July 7, 2007.

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